PT. SINKO PRIMA ALLOY

Alamat	: Jl. Tambak Osowilangun Permai No. 61, pergudangan osowilangun permai Blok E7-E8, Surabaya-Indonesia (60191)
Telepon	: 031-7482816
Fax.	: 031-7482815
Aftersale (WA)	: 0821-4281-7085
Email	: aftersales@elitech.co.id sinkoprima@gmail.com
Website	: www.elitech.id

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Contents

1 Summary

Jaundice is a common phenomenon in neonatal period, it is observed that over 90% newborn babies have jaundice in different degree. It can be a physiological phenomenon (called physiological jaundice) in neonatal period, or it can be an important symptom of many diseases in neonatal period （called pathological jaundice）. This pathological jaundice can cause bilirubin brain illness (called kernicterus), it can cause brain damage of newborn baby, and results in early death and serious sequela, so we must take immediate and efficient measures to treat neonatal pathological jaundice.

The effect of phototherapy treatment for neonatal high bilirubin blood illness has been approved by clinic, its principle is that bilirubin can absorb rays to have actinic isomerization, it makes the indirect bilirubin oxidize into one water-soluble product under the bluish green light (light-oxidation bilirubin). It fades yellow according to liver and gallbladder discharging out of body. The medical field recognizes that using phototherapy to treat neonatal pathological jaundice is a simple and effective method. Neonatal phototherapy unit are also called “infant phototherapy device” or “blue light lamp”. It is necessary medical equipment of neonatal medical department.

1.1 Definition and Symbol

1.1.1 Definition

The terms and definitions of IEC 60601-2-50 "Medical Electrical Equipment Part 2: Special Requirements for the Safety of Infant Phototherapy Equipment" apply.

1、Effective surface

Place the patient according to the designated position on the surface irradiated by the phototherapy equipment.

2、Total bilirubin irradiance Ebi

The irradiance is equivalent to the irradiance evaluated in the range of 400nm～550nm, and is given by the following integral formula:

Ebi = $\int_{400nm}^{550nm} E_\lambda(\lambda)d\lambda$

unit：μW/cm²，Where Eλ(λ) is the irradiance measured at each wavelength.

3、Uniformity of bilirubin total irradiance G2

The ratio of the minimum total bilirubin irradiance Ebi min and the maximum total bilirubin irradiance Ebi max on the effective surface is as follows: G2 = Ebi min/EBi nmax

4. Air temperature

The air temperature 10cm above the center of the baby bed in the box.

5、Skin temperature

The temperature where the skin temperature sensor is placed on the baby's skin.

1.1.2 Symbol mark

	Eye Protection for the patients		Attention, Consult accompanying documents
	Power on		Power off
	Type BF application part		Alarm sound pause button
	Increase key		Decrease key
	Key		Timing start/stop button
	Phototherapy working mode key		Battery

	Low priority alarm		High priority alarm
	Conforms to WEEE EU Directive		

1.2 Scope of application and contraindications

1.2.1 Scope of application

This product is used for light treatment of high bilirubin for newborn baby.

1.2.2 Contraindications

a) Do not use this product to irradiate patients whose temperature is too high (≥37.7℃)!

b) Prohibited patients with elevated bilirubin!

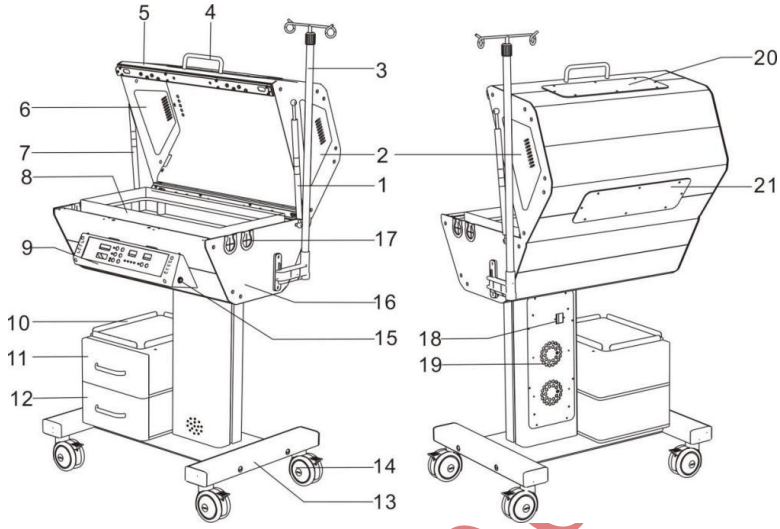
1.3 Structure composition and characteristics

1.3.1 Structural composition

BL-360 baby phototherapy instrument (hereinafter referred to as light therapy instrument) is composed of blue light, control box, box (including crib), support rod, base and accessories (skin temperature sensor, etc.).

The crib is made of high-quality Plexiglas; the upper and lower parts of the box are equipped with high-efficiency blue light strips.

The main parts of the equipment are shown in the figure below:



1. Right pole	2.Right observation	3 .Infusion support
4.Phototherapy	5.Up phototherapy	6.Left observation
7. Left pole	8. Infant bed	9 .Operation panel
10. Tray	11. Upside drawer	12.Downside drawer
13. Phototherapy unit base	14. Wheel	15.Temperature sensor socket
16. Down	17. Transfusion seal	18. Power socket
19. Inlet	20.Front observation	21.Back observation

Figure 1-1 Schematic diagram of the main structure of the phototherapy instrument

Part Name	Description
Base	Used to carry the weight of the box and accessories.

Box	Including the upper blue light box, the lower blue light box and the crib, the crib is used to support the child, the maximum load capacity is 100N.
Control box	An important part of the equipment, the control box is composed of a control box shell, a control circuit board and an operation panel. Used to control the blue light.
Tray	Used to place care products. The maximum load weight is 20N.
Drawer	Used to store medical supplies and documents. The maximum carrying capacity of a single drawer is 20N.
Skin temperature sensor socket	Used to connect the skin temperature sensor to measure the baby's skin temperature.

1.3.2 Features

1. Small size, flexible movement and high irradiation efficiency.
2. LED is a cold light source with uniform irradiation, high efficiency and long life.
3. Separate screen to display the upper and lower blue light treatment time independently.
4. Up and down light working modes are independently selectable.
5. Independent display of box temperature and skin temperature.
6. There are power-off memory, fault alarm silence, keyboard lock and self-check functions.
7. Four safety function alarms: power failure, fan, over temperature, sensor.
8. Countdown timer function.
9. Automatically save 99999.9 hours of accumulated use time.
10. Double-sided observation window, convenient to observe the baby's treatment status at any time.

11. The box body adopts the gas spring structure, and the phototherapy instrument can be opened and closed easily and labor-saving.
12. The cabinet and base are made of high-grade magnesium-aluminum alloy, which will never rust.

1.4 Equipment classification

Figure 1-4 Product classification

Classified by type of electric shock prevention	Class I
Classified by degree of protection against electric shock	Type BF
Classified according to the degree of protection against ingress of liquid	IPX4（The lower part of the infant bed）
Whether AP, APG type	Non-AP, APG equipment
Classified by operating mode	continue to operate

1.5 Working and transportation storage conditions

Figure1-2 Working, Transportation and Storage

Working environment conditions	Temperature	18℃～30℃
	Humidity range	10%～85%RH
	Atmospheric pressure range	700hPa～1060hPa
Environmental conditions for transportation	Temperature	-10℃～+55℃
	Humidity range	≤95%

and storage	Atmospheric pressure range	500hPa～1060hPa

The outer packaging box of the product can be transported by general transportation means, and it should be handled with care when transporting, and it should be kept upright and moisture-proof during transportation.

1.6 Period of use

1、Product life: 6 years.

2、Production date: See product label.

2 Working Principle

The therapy instrument is hexagonal, and it is divided into upper and lower parts. The 8 blue LED light bars distributed in the box constitute the upper and lower parts of the blue light irradiation light source, and the upper and lower parts of the box constitute an upper light source room and a lower light source room respectively. The upper light source chamber can be pulled up by the handle, and the gas spring forms an effective fixed support structure. The net cover of the crib adopts a permeable net structure, which is conducive to the blue light irradiation treatment of the lower part.

When the LED lights in the upper and lower light source rooms emit blue light for treatment, they also generate a certain amount of heat radiation, so that the air temperature in the box gradually rises to the environmental temperature required for treatment. The LED lamp driving circuit and the fan cooling system are located in the lower part of the base. The cooling system takes away the excess heat of the system through the air duct connected by the upper and lower light source chambers, so that the system maintains the treatment environment temperature relatively stable. The control circuit is located inside the operation panel. Medical staff select the appropriate irradiation mode and timing method according to clinical needs, and

monitor the skin temperature according to the panel display, which can safely and effectively treat neonatal jaundice.

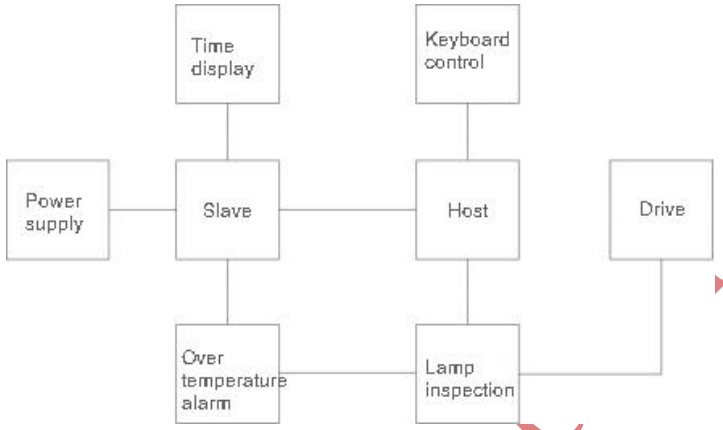


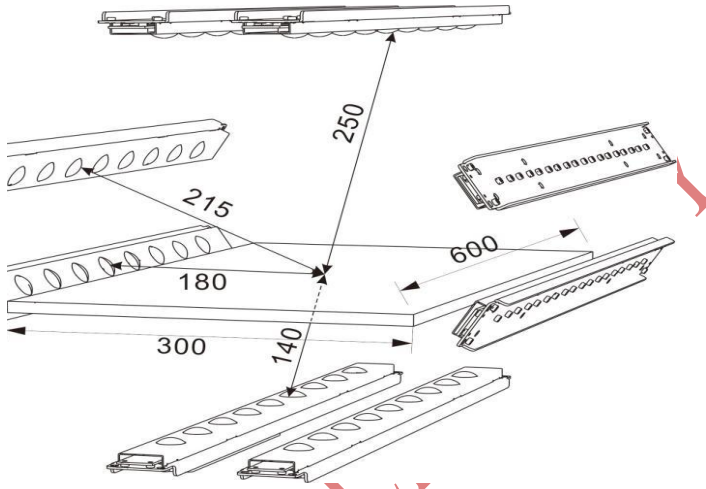
Figure 5-1 System principle block diagram

3 Performance

Figure 3-1 Main performance indicators

Product	BL-360	
Power supply	AC 220V±22V；50Hz±1Hz	
Input power	103VA	
Radiant wave	420nm～490nm	
Total bilirubin irradiance(μw/cm²)	Upside phototherapy	3980
	Downside phototherapy	3300
Uniformity of total irradiance of bilirubin	＞0.4	
Positive	0-100h/1s；	
Count down time	0-100h/1s；	
Accumulate time	0-99999.9h/0.1h；	
Noise	During normal operation, the sound level of the baby bed surface is ≤55dB(A); when the alarm is issued, the sound level in the infant cabin is ≤80dB(A); when the alarm is issued, the sound level 3m in front of the equipment is ≥65dB(A);	
Air temperature display range	10℃～45℃；	
Air temperature reading error	In the range of 32℃-37℃, the reading error should be within ±0.8℃	
Skin temperature display range	30℃～45℃	

Accuracy of skin temperature sensor	In the range of 30℃-40℃,accuracy within ±0.3℃



unit：mm

Figure 6-1 Schematic diagram of the effective surface size and its position relative to the device

4 Function description

4.1 Main function or working mode

The device has 3 working modes: ①upside phototherapy mode: upper timing, upper blue light is on; ②downside phototherapy mode: lower timing, lower blue light is on; ③ upper and lower blue mode: timing up and down at the same time, upper and lower blue lights are on.

4.2 Alarm function

4.2.1 Overview

Ensure to provide a suitable temperature environment for the treatment of jaundice in children; in the use and maintenance of the equipment, the user can be notified in time when there is a failure, so that effective measures can be taken

quickly to reduce and avoid harm to the patient. The equipment has 4 alarm states, namely: power failure alarm, sensor alarm, over-temperature alarm, and fan alarm. In the over-temperature alarm, the skin temperature over-temperature alarm belongs to the physiological alarm state, the power-off alarm belongs to other alarm states, and the other alarms belong to the technical alarm state.

Figure 4 -1 Alarm status description

Alarm status	Alarm activation conditions	Status description	Status description
Power failure alarm	After the device's power switch is turned on, if the device's AC power supply is interrupted, the device will sound an audible and visual alarm for at least 10 minutes or until the power supply is restored.	The device emits a "dididi..." audible alarm, and the "power off" red indicator light on the control panel is flashing, and all other digital displays and indicators are off, and the device enters the "power off" alarm state.	Not more than 3s; The operator is located within 1 meter in front of the equipment.

Sensor alarm	If the air temperature sensor or skin temperature sensor is open or short-circuited, the device will give out an audible and visual alarm and cut off the upper and lower blue light power supplies.	1. The device sends out a "beep beep... beep, beep beep..." audible alarm, except for the "sensor" red indicator on the control panel flashing, other alarm indicators are off, and the skin temperature is displayed The window has no display, and the box temperature display window displays normally, indicating that it has entered the "skin temperature sensor failure" state; 2. The device emits a "beep beep... beep beep, beep beep..." beep, the red indicator light of the "sensor" on the control panel flashes, other alarm indicators are off, and the box temperature display window There is no display, and the skin temperature display window displays normally, indicating that it has entered the "box temperature sensor	Not more than 5s; The operator is located within 1 meter in front of the equipment.

		failure" state. 3. When the device emits a "beep beep... beep, beep beep... beep,..." an audible alarm, the "sensor" red indicator on the control panel flashes, other alarm indicators are off, and the box is gentle The skin temperature display window has no display at the same time, indicating that it has entered the "box temperature, skin temperature sensor failure" state.	
Fan alarm	If the fan stops abnormally or the fan sensor system fails, the device will give an audible and visual alarm and cut off the upper and lower blue light power supplies.	The device emits a "beep... beep, beep... beep,..." audible alarm, the "fan" yellow indicator on the control panel is always on, and other alarm indicators are off, indicating that it has entered "fan failure" status.	Not more than 3s; The operator is located within 1 meter in front of the equipment.

Over temperatu-re alarm	1) When the upper and lower blue light mode, if the box temperature exceeds 37.5 ℃, the device will automatically sound and light alarm and cut off the blue light power. 2) When in the blue light mode or the blue light mode, if the box temperature reaches 37℃, the device will automatically send out an audible and visual alarm and cut off the blue light power supply. 3) If the skin temperature reaches 38℃, the device will automatically send out an audible and visual alarm and cut off the upper	The device emits a "beep beep... beep, beep beep... beep..." an audible alarm, and the "over temperature" red indicator on the control panel flashes and lights up, and other alarm indicators are off. The temperature or skin temperature display window displays a higher actual temperature value, and the device enters the "over temperature" alarm state.	Not more than 5s; The operator is located within 1 meter in front of the equipment.

	and lower blue light power supplies. 4) If the box temperature reaches 39.5℃, the equipment will automatically sound and light alarm, and the thermal circuit breaker will cut off the upper and lower blue light power supplies.		

4.2.2 Time to verify whether the alarm system is normal

After the equipment is installed for the first time or after the components are disassembled and reinstalled due to cleaning and maintenance, and before use, it is necessary to verify whether the alarm system of the equipment is normal. For the verification method, see 4.2.4 Function Inspection.

4.2.3 Priority of alarm status

According to Part 1-8 of IEC 60601-2-50 Medical Electrical Equipment, the alarm state of the equipment must not only produce a visual alarm signal that meets the requirements, but also an audible alarm signal that meets the requirements to ensure the safety of patients.

The priority of the equipment alarm status and the characteristics of the alarm signal are shown in Figure 4-2.

Figure 4-2 Priority of alarm status and alarm signal characteristics

Alarm status	Priority	Visual alarm	Audible alarm

		colour	Flashing frequency （Hz）	Number of pulses in pulse group	Burst interval（S）
Power off	high	red	1.4Hz-2.8 Hz	-	-
Over tempe-rature	high	red	1.4Hz-2.8 Hz	10	2.5s-15.0s
Air temperature, skin temperature sensor	high	red	1.4Hz-2.8 Hz	10	2.5s-15.0s
Fan	low	yellow	Always on	2	＞15s

Note:

1. The sound alarm of power failure alarm is different from other high-priority alarms, and its source is a single buzzer;

2. When the power loss time does not exceed 30s, the alarm setting before the power loss is automatically restored, and the power loss will not cause the loss of the alarm setting

3. Sound pressure range of audible alarm signal: high priority ≥ low priority ≥ 65dB (A);

4. If there are multiple alarm states at the same time, the device will give an audible alarm to the alarm state with a higher priority and a visual alarm at the same time.

5. Except for power failure alarms, all other alarms can be muted by the alarm sound pause button for 5 minutes. During the mute period, press the alarm sound pause button again to release the mute state. After the alarm is muted, if the alarm source still exists, the alarm will be reactivated;

6. The second over-temperature is a latching alarm signal. After the fault is removed, the machine must be restarted to clear the alarm.

Warning: The same or similar equipment used in any independent area may be potentially dangerous if different alarm presets are used.

4.2.4 Function check

After the equipment is installed for the first time or after the components are disassembled and reinstalled due to cleaning and maintenance, and before use, the equipment needs to be functionally checked to ensure the safe use of the equipment.

1. Power failure alarm inspection

Before the power plug of the equipment is plugged into the AC power socket, turn on the power switch, the equipment should appear "power off" sound and light alarm, after turning off the power switch, the alarm will be cleared.

2. Skin temperature sensor alarm test

After the power switch is turned on, unplug the skin temperature sensor (or unscrew the sensor plug and short-circuit the connecting wire), the sound and light alarm of the sensor should appear, re-plug the skin temperature sensor (or remove the short wire), the alarm will be automatically released and the equipment will be restored Normal working condition.

3. Inspection of over-temperature alarm function

When the equipment is working, use a hot air gun or soak in warm water to increase the temperature of the box temperature sensor to 37°C (upper blue mode or lower blue mode) or 37.5°C (upper and lower blue mode) or the skin temperature sensor to 38°C. Displayed through the box temperature or skin temperature display window, the device should give an over-temperature audible and visual alarm and cut off the upper and lower blue light power sources. When the box temperature is lower than 36°C (upper and lower blue light mode is 36.5°C), the alarm is released and the skin temperature generates over-temperature alarm. The relief is based on the box temperature.

4. The second over-temperature alarm circuit breaker inspection

Select the second over-temperature test mode: After selecting the lock, press the key button for a few seconds, the skin temperature display window will display --- cooperate with the plus and minus keys, press the mute key for displacement, enter the 456 password, after the key is confirmed, the box temperature The display window displays 0, and press the plus key to input 1, and the key is used to confirm. The box temperature and skin temperature display windows are displayed normally, the over-temperature warning light is flashing, and the second over-temperature test

mode is entered. When the box temperature reaches 39.5°C, an over-temperature sound and light alarm should appear and the upper and lower blue light power supplies should be automatically cut off. After the temperature drops to 37.5°C, restart the machine to release the over-temperature alarm state.

5. Inspection of fan failure alarm function

When the fan is running normally, the fan is prevented from rotating. After about 2 seconds, the device will send out an audible and visual alarm and cut off the upper and lower blue power sources. The alarm will be automatically cleared after the fan resumes rotation.

5 Installation

5.1 Unpacking and installation

1. Take out the equipment from the packing box. The host is packaged as a whole and does not need to be installed.
2. Take out the skin temperature sensor from the packing box and insert it into the skin temperature sensor socket of the device.
3. Take out the power cord from the packing box, plug one end into the input jack of the device, and connect the other end to the network power supply.
4. The installation is complete.

Figure 5-1 Skin temperature sensor

Figure5-2 Skin temperature sensor socket

Note:

1. Please make sure that the skin temperature sensor has been installed on the device before starting the machine, and make sure that the skin temperature sensor plug-in is in place and well connected. Otherwise, the device will not work normally.
2. Be careful not to pinch your hands when closing

6 Instruction for use

6.1 Introduction to panel switches and sensors

1、Power switch

Under the premise that the device is connected to the network power supply and the skin temperature sensor is correctly installed, turn on the power switch and the device works normally. When the device is not connected to the network power supply and the power switch is turned on, the device power failure alarm will be activated.

The power switch of the equipment is located on the side of the equipment control cabinet, below the equipment handle. as the picture shows:

Figure 6-1 Power switch

2、Fuse holder

Marking: T 2AL 250V means that the model of the fuse is T 2AL 250V.

When the fuse tube is damaged, please replace it in time, otherwise it will affect the normal use of the machine. See 12.2.2 below for the specific replacement method.

3、Power input socket

The power input socket is a single-phase three-hole socket. When using this equipment, you must ensure that the ground wire of the network power supply is reliably grounded.

4、Skin temperature sensor socket

1 Skin temperature sensor socket

Provide the device with the purpose of inserting a skin temperature sensor. Before inserting the skin temperature sensor, check whether the connector of the skin temperature sensor is clean. If there is dust, wipe it clean to avoid the device alarming due to poor contact after the sensor is inserted.

Note: When inserting the sensor, the protrusion of the plug should face the notch on the socket.

2. Use skin temperature sensor correctly

When using a skin temperature sensor, you must ensure that the probe of the skin temperature sensor is in reliable contact with the patient's skin. If the patient is lying on his back, the probe should be placed between the sword-shaped cartilage of the patient's abdomen and the belly button. Care should be taken to avoid the liver. If the patient is lying prone, the probe should be placed on the patient's back, preferably in the kidney area; for patients lying on the side, the specific location of the probe, please follow the instructions of the attending doctor.

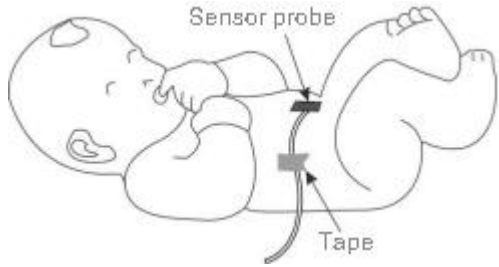


Figure 6-4 Schematic diagram of the use of skin temperature sensor probe

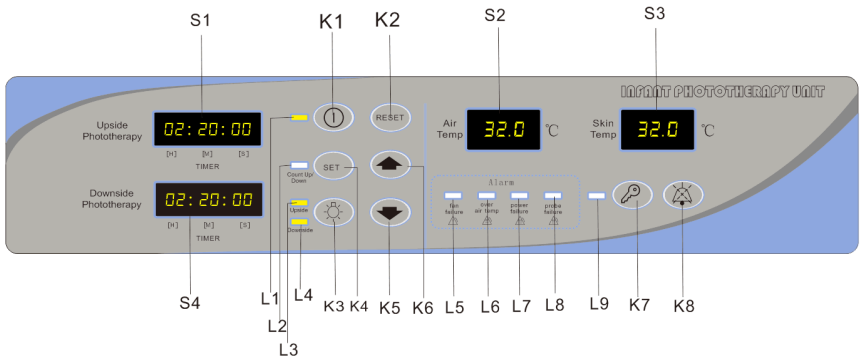
Note:

1. The probe of the skin temperature sensor cannot be used as a rectal thermometer.
2. Every time a child is treated, the skin temperature sensor must be disinfected before it can be used again.
3. Do not place the skin temperature sensor under the patient.

Warning

1. When using a skin temperature sensor, you must ensure that the skin temperature sensor probe is in reliable contact with the appropriate part of the patient. If the probe is detached from the patient, the temperature measured by the sensor at this time is not the expected patient skin temperature. It could be the air temperature or the surface temperature of the mattress.
2. The skin temperature sensor measures the patient's skin temperature, not the patient's actual body temperature. Therefore, the skin temperature sensor cannot be used as a clinical thermometer. During treatment, the patient's body temperature must be measured regularly with a thermometer to determine whether the patient has obvious signs of fever or cooling.
3. Please do not cover blankets, diapers and other objects on the skin temperature sensor probe, otherwise it will affect the accuracy of temperature measurement.

6.2 Operation panel Description



L1 Timing start indicate
L2 Count down indicate
L3 Upside timing indicate
L4 Downside light timing indicate
L5 Fan failure alarm indication
L6 Over air temperature alarm indication
L7 Power failure alarm indication
L8 Probe alarm indication
L9 lock indication
S1 Upside phototherapy timing show
S2 Air temperature show
S3 Skin temperature show
S4 Downside phototherapy timing show
K1 Timing start / stop
K2 Timing reset / delete button
K3 Phototherapy working mode button
K4 Count down set up button
K5 Reduce key
K6 Increase key
K7 Key button
K8 Audio paused key

6.3 Operating instructions

1. Unlocking and locking

Press K7 (key button) can alternately choice unlocking, locking state, L9 (lock indication) green light pull out means already unlocking, L9 (lock indication) green light bright show already lock. When unlock state, if no key operation 30 second, system will lock automatically.

2. Timing start or stop

After unlock, press K1 (timing start / stop key) can alternate choice start, stop state, L1 (timing start indication) green light bright show already start the timing (turn on the phototherapy light automatically), L1 (timing start indicate) green light put out means already stop timing (turn off the phototherapy light automatically)

3. Working mode choice

After unlock, choice timing stop state, press K3 (phototherapy working mode key), can alternate choice up phototherapy timing (L3 (up phototherapy light timing show) green light bright); down phototherapy timing (L4 (down phototherapy timing indicate) green light bright); up and down phototherapy together timing (L3, L4 light bright) three phototherapy working mode.

Attention: adjust phototherapy working mode should in the air temperature keep in relatively stable temperature range proceed.

4、Countdown setting:

After unlocking, select the timing pause state, determine the work mode, press the countdown setting button, the setting indicator light is on, the two digits on the left side of the timing window flash, and press the plus and minus keys to set the "hour" time. Press the set button again, the two digits in the middle of the timing window flash, cooperate, plus and minus keys can set the "minute" time, press the set button again after completion, the two digits on the right side of the timing window flash, cooperate, and add keys, Minus key can set the "second" time. After the setting is completed, press the timer start button to start the countdown (automatically turn on the blue light), the countdown time setting value is automatically memorized (not memorized if the start button is not pressed), and the corresponding blue light is automatically turned off after the countdown is reset to zero.

Prompt:

1) If the up and down countdown settings are different, and one of them has been reset to zero during the countdown, the system will be locked, and the mode cannot be changed at this time. The locked state can be released after the countdown is all reset to zero or the timer clear key is pressed.

2) If the up and down countdown settings are different, and one of them has been reset to zero during the countdown, the system will be locked. If you pause and restart the countdown at this time, the reset timer will be in a waiting state and will not count down again. Wait for another timer to reset to zero or press the timer clear key to release the locked state, and then restart the countdown to restore the timer.

3) During the countdown, if you press Unlock ---- the timing stops, and then press the set button, the countdown will be reset to the preset value.

5、Switch between positive and countdown:

After unlocking, select the timing pause state, if it is currently "counting up" and want to switch to "counting down", you can press the set button, the countdown indicator will light up in green, and the timing window will display the countdown setting value. If it is currently "countdown" and need to switch to "positive timing", you can press the timer reset/clear key, and the countdown indicator will turn off green.

6、View the total cumulative time and total cumulative clear:

View and clear in menu 8 and menu 9 (see the description in the following menu chapters for details).

7、Timing and clearing

After the "positive timing" starts (automatically turn on the blue light), when the maximum time value of 99H.59M.59 is counted, it will automatically stop (and automatically turn off the blue light). If you want to clear the "positive timing value", you can choose to pause the timer. Long press the timer reset/clear button to clear the timer window.

8. Alarm silence:

When a fault alarm occurs, press the alarm sound pause button (not controlled by the lock key), the alarm mute indicator light is on, and the alarm sound is paused.

Press the alarm silence pause button again or no operation for 5 minutes, if the alarm source still exists, the alarm will be reactivated.

9. Menu operation:

After choosing to lock, then press and hold the lock button for a few seconds, the skin temperature display window will display --- cooperate with the plus and minus keys, press the mute key, enter the 123 password, the key is OK to enter the system setting menu, you can select Pr.1 Pr.2 Pr.3 Pr.4 Pr.5 Pr.6Pr.7 Pr.8Pr.9 Perform different functional operations.

Warning: It is forbidden for operators and other unauthorized personnel to access and store changes!

Function Description

Pr.1 function 1: air temperature, skin temperature error correction P20（0-4.0 P20（0-4.0）

Operation key: K7 (key button) --- function operation, K6 (increase key), K5 (reduce key) --- choice

Pr.2 function 2: hardware test

Operation key: K7 (key button) ---function operation, K6 (increase key) ---choice

Skin temperature display window	Test item
01	Upper and lower light protective relay switch on
02	up and down light BTA switch on
03	Fan switch on 100%
04	LED light all bright（except outage alarm light）
05	Buzzer ring
06	Action hardware all close

Pr.3 function 3: check the second cut-off sensor real-time temperature

Operation key: K7 (key button)—function operation, K6 (increase key) --- choice

Pr.4 function 4: check the second cut-off temperature alarm set up default

Operation key: K7 (key button) --- function operation, K6 (increase key) — choice

Pr.5 function 5: fan 1 checking

Operation key: K7 (key button) — function operation, K6 (increase key) --- choice

Pr.6 function 6: fan 2 checking

Operation key: K7 (key button) — function operation, K6 (increase key) — choice

Pr.7 function 7: key function checking

Operation key: K7 (key button) — function operation, K6 (increase key) — choice

Attention: go into function 7, except K7 (key button) can quit menu, press other anyone key can show one" toot" sound. Means key is normal

Pr.8 function 8: check the cumulative time

Operation key: K7 (key button) --- function operation, K6 (increase key) — choice

Pr.9 function 9: clear all the cumulative time (cumulative time unit is hour)

Operation key: K7 (key button) — function operation, K6 (increase key) — choice

Attention: go into pr.9 function 9, one more item should confirm, press K6 (increase key) choice "0" or "1", "0" means not take this operation, "1" will take clear operation. (Carefully use it)

6.4 Temperature and fan control

1. Up and down phototherapy mode:

(1) When the air temperature rises to 35.5°C, the fan starts to rotate at a high speed. When the box temperature rises to 36.5°C, the lower blue light turns off. When the box temperature is greater than 37.5°C, the lights will be turned off and an over-temperature audible and visual alarm will be issued.

(2) When the temperature of the box drops to 36.5℃, the upper blue light will be turned on automatically. When the temperature drops to 36°C, the closed blue light turns on., When the temperature drops to 35.5°C, the fan turns off.

2. Up phototherapy Mode and Down Phototherapy Mode:

(1) When the air temperature rises to 36.0℃, the fan starts to rotate at a high speed. When the box temperature exceeds 37.0℃, the light will be turned off, and the over-temperature sound and light alarm will be given.

(2) When the air temperature drops to 36.0℃, the blue light will be automatically restored and the fan will be turned off.

3. Skin temperature control:

(1) When the skin temperature rises above 38.0℃, the lights will be turned off and the over-temperature sound and light alarm will be issued;

(2) Skin temperature is not controlled downward. Whether to restore or not depends on the box temperature control.

4. The second cut-off temperature is 39.5°C.

5. When the power is off, the fan and sensor will automatically resume work after the alarm failure is removed.

7 Precautions

7.1 Can only be used by appropriately trained personnel and qualified medical personnel who are familiar with the existing known risks and benefits of using the equipment

7.2 The use of phototherapy equipment may affect the patient's body temperature, and it is necessary to measure the patient's body temperature; phototherapy may also affect the water balance of some patients, and appropriate supplementary fluids are required to prevent patients from being dehydrated.

7.3 In order to ensure the safety of children, do not leave the children unattended in the equipment. When the instrument is working, the operator must always pay attention to the patient's condition, and regularly monitor and record the patient's temperature during the treatment process to see if there is any abnormality such as over-cooling or over-heating.

7.4 The use of phototherapy equipment in thermotherapy devices (such as incubators, radiation heaters, heating mattresses) increases the amount of heat supply, which will affect the patient's body temperature and may increase the patient's body temperature. Therefore, when performing phototherapy, the temperature of the child must be measured regularly.

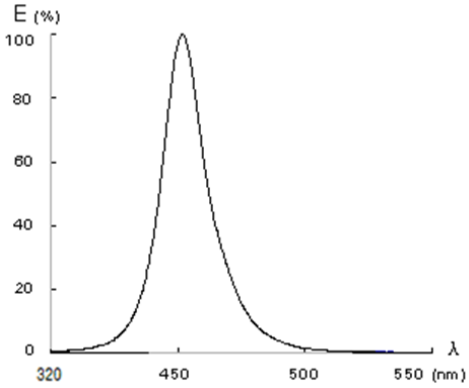
7.5 When using infant incubators, infant radiant warmers or heated mattresses, it is recommended to use the infant skin control mode. Otherwise, according to the body temperature measurement result, the setting value of the air temperature in the incubator or the setting of the heat output of the radiant warmer or the setting of the heat output of the heated mattress must be reduced.

7.6 The service life of the LED lamp beads is 50000 hours. When the cumulative work of the lamp beads reaches the expected life, all the LED lamp beads must be replaced to ensure the treatment effect. When replacing the lamp beads, the special LED lamp beads designated by the manufacturer must be used, otherwise the safety and effectiveness of the phototherapy equipment will be affected.

7.7 The maintenance period of LED lamp beads is 2 months, to ensure that all LED lamp beads are replaced after the total bilirubin irradiance has attenuated by 25%.

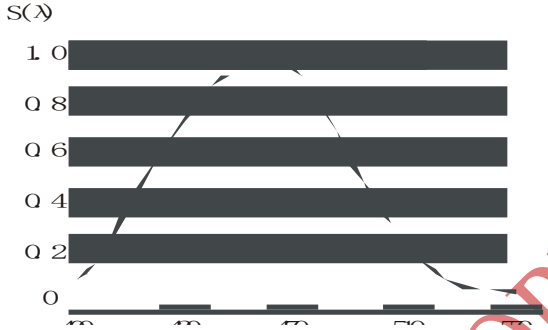
7.8 As the distance between the phototherapy equipment and the effective surface increases, the average value of the total bilirubin irradiance will decrease; as the distance decreases, the average value of the total irradiance will increase.

The figure below shows the irradiance curve with a wavelength range of 320nm to 550nm and an interval of 5nm.



7.9 The calibration curve of the blue radiometer for measuring the total irradiance of bilirubin is shown in the figure below. The abscissa represents the

wavelength of the radiation, and the ordinate represents the spectral sensitivity of the blue radiometer.



7.10 During phototherapy, the photo isomer of bilirubin may cause toxic effects.

7.11 Patients may need protection when they are close to the phototherapy equipment. Protective measures such as protective covers and goggles should be provided in time.

7.12 During phototherapy, the patient's bilirubin value should be measured regularly.

7.13 As long as the eyes of the patient may be exposed to the radiation of the phototherapy equipment, immediately provide the patient with an eye mask for protection.

7.14 The equipment warm-up time is 30min.

7.15 Protective devices (such as cribs, guard rails, front doors, etc.) that are expected to prevent patients from leaving the effective surface area must be regularly checked for their safety functions.

7.16 The changes of the patient's surrounding environmental conditions (such as environmental temperature, different radiation sources, etc.) will affect the treatment effect.

7.17 The service life of this equipment is 6 years. After the expiration of the period of use, if discarded randomly, it will cause damage to the local environment. Therefore, it must be disposed of in accordance with local laws or returned to our company for disposal.

7.18 The brake casters must be locked during use to prevent the equipment from moving.

7.19 Only use the parts designated by our company (including adapters and LED lamp beads) during product maintenance, otherwise the safety and effectiveness of the equipment will be affected.

7.20 For newborns suffering from severe jaundice, phototherapy should also be combined with drugs, or even combined with exchange blood therapy, to prevent the unsatisfactory effect of phototherapy alone from affecting the treatment of children.

7.21 When observing the baby's skin color for diagnosis, a white light source should be used to prevent the use of blue light from affecting the skin color observation.

7.22 Do not use it in an environment with portable and mobile radio frequency communication equipment, so as not to affect the normal operation of the product.

7.23 The use of opaque curtains to protect the children will affect the care and observation of the children by the nursing staff. It is recommended to increase the frequency of monitoring children, and if necessary, keep the transparent observation window for real-time observation.

7.24 In clinical application, the operator needs to pay attention to the change of the box temperature, and take appropriate measures when necessary according to the change of the box temperature.

8 Warning

8.1 This equipment is only used for blue light irradiation treatment and cannot be used as an infant incubator.

8.2 During phototherapy, the child’s eyes must be covered with an opaque black cloth or goggles should be worn to avoid damage to the patient’s retina during light exposure. The tightness of the goggles should be appropriate.

8.3 During phototherapy, the skin of the child should be bare, hats and socks will also affect the effect of phototherapy, diapers should be used to cover the genitals to prevent damage to the genital function.

8.4 If the operator stays in the irradiation area of the phototherapy device for too long, it may also be affected.

8.5 It is forbidden to use flammable agents (preservatives, cleaning agents, etc.) on phototherapy equipment.

8.6 It is forbidden to store medicines and injections in the radiation area of the phototherapy apparatus.

8.7 Light therapy equipment cannot be used in the presence of combustion-supporting gases (such as oxygen, nitric oxide, anesthetic gases).

8.8 It is strictly forbidden to place objects on the radiation box of the equipment, let alone liquid substances, and it is strictly forbidden to cover the radiating holes of the radiation box.

8.9 In the process of phototherapy, adverse reactions such as abnormal body temperature, diarrhea, skin rash, and bronze syndrome may occur. Medical staff should pay close attention to the situation of the child and take corresponding treatment measures for adverse reactions.

8.10 As the device connection method adopts a gas spring structure, the device should be slowly opened or closed to avoid excessive speed that may cause injury to the patient and the operator.

8.11 This equipment is only used for blue light irradiation treatment and cannot be used as an infant incubator.

8.12 Direct sunlight or other radiant heat sources will increase the temperature of the equipment, but will not activate the over-temperature alarm function of the equipment. Therefore, avoid direct sunlight and keep away from radiant heat sources during the use of the equipment

9 Cleaning and maintenance

Warning: Before performing cleaning and maintenance, you must cut off the link with the power supply and turn off all power switches.

9.1 Cleaning and disinfection

The equipment must be thoroughly cleaned and disinfected when the equipment is used for the first time, or after the irradiation of an infant is completed, or when the equipment has been used continuously for one week.

It is recommended to use a neutral disinfectant (such as 84 disinfectant) to disinfect according to the concentration and time diluted in the product manual.

Cleaning and disinfection of equipment surface:

1. Hold the handle of the device and pull it up to open the device.
2. First use a clean cloth to thoroughly wipe all surfaces, including corners and edges, then wipe and disinfect with a cloth moistened with disinfectant, and finally wipe dry with a disinfectant cloth. Do not scrub with organic solvents such as alcohol. Do not expose the equipment to direct ultraviolet radiation.

Cleaning and disinfection of cribs:

1. Hold the handle of the device and pull it up to turn on the device.
2. Hold the edge of the crib with both hands and take out the crib.
3. First use a clean cloth to wipe all surfaces of the crib thoroughly, then wipe and disinfect with a cloth moistened with a disinfectant, and finally wipe dry with a disinfectant cloth.

After cleaning and disinfection, reassemble it according to the above method.

Cleaning and disinfection of skin temperature sensor:

First, wipe the surface of the skin temperature sensor thoroughly with a clean cloth, then wipe and disinfect with a cloth moistened with a disinfectant, and finally wipe it dry with a disinfectant cloth.

9.2 Maintains

When the machine is not in use, unplug the power plug and do not connect to the mains power supply. Use a cleaning cloth to wipe the surface of the whole machine, especially the transparent surface must not be polluted by dirt to keep it bright and clean. When not in use, use a breathable cloth cover to cover the unit for storage.

Replacement of fuse tube

This machine uses a T2.0AL 250V, Φ5×20 fuse tube. When replacing the fuse tube and repairing, you must first unplug the power cord, then pull out the fuse tube holder, and take out the broken fuse tube. Professionals use the same Replace the fuse tube of the model (see the figure below).

（1）Replacement of fuse tube

The fuse holder of the device is located behind the column of the device.

Unplug the power cord, use a screwdriver to unscrew the fuse cover on the fuse holder, and replace it with a new T2.0AL 250V, Φ5×20 fuse.

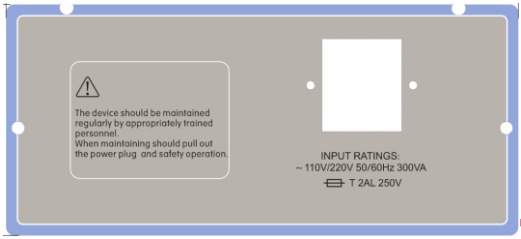


Figure 9-1 Power socket (with fuse holder)

（2）Replacement of the fuse tube in the power socket

Use a small flat-blade screwdriver to pry open the fuse holder of the power socket, as shown in the figure below

Use a small flat-blade screwdriver to insert the fuse holder of the power socket from below and push out the fuse as shown in the figure below

Replace with a fuse tube of T2.0AL 250V, Φ5×20.

Use a small flat-blade screwdriver to pry open the power socket fuse holder

The skin temperature sensor is recommended to be replaced every two years to avoid damage to the surface and firmness of the sensor caused by long-term use and disinfection.

Battery replacement:

① If the equipment has not been used for more than three months, it should be turned on and the machine will automatically charge for more than six hours to ensure that the power supply is sufficient for power failure.

②Perform a power failure alarm test before each use of the equipment. If you find that the audible alarm does not sound, or the alarm sound is too low or the alarm sound is abnormal, the battery must be maintained in time. If the battery fluid is found to flow out, it must be cleaned with detergent to avoid Corrosion equipment. When replacing the battery, first unplug the power cord, and then solder a new battery with the model specification of B80H5A2H 8.4V on the circuit board according to the marked polarity. Don't throw away the replaced batteries randomly. Collect them together to avoid environmental pollution.

Maintenance of LED lamp beads:

The total bilirubin irradiance of the equipment should be tested at least once every 2 months. The test should be carried out by authorized personnel with sufficient professional knowledge and practical experience or contact the manufacturer for testing. If the total bilirubin irradiance is attenuated by 25%, To replace all LED lamp beads immediately (blue lamp bead model: SMD5050), it should be replaced by professionals.

Maintenance of the whole machine:

The following inspections of the equipment shall be carried out at least every 12 months. The test shall be carried out by authorized personnel with sufficient professional knowledge and practical experience, or the manufacturer shall be contacted for the test. If it is unqualified, it shall be repaired.

√ Check the integrity of the mechanical structure and function.

√ The protective grounding resistance impedance of the test equipment should not exceed 0.1Ω

√ The earth leakage current of the test equipment should not exceed 500μA under normal conditions, and should not exceed 1000μA under a single fault.

√ The shell leakage current of the test equipment should not exceed 100μA under normal conditions, and should not exceed 500μA under a single fault.

√ The patient leakage current of the test equipment should not exceed 100μA in AC and 10μA in DC under normal conditions.

√ The patient leakage current of the test equipment should not exceed 500μA in AC under a single fault condition, and the DC should not exceed 50μA under a single fault condition.

√ The patient leakage current of the test equipment, (applied part of the grid voltage), should not be greater than 5000μA under a single fault.

√ The patient auxiliary current of the test equipment should be no more than 100μA in AC and no more than 10μA in DC under normal conditions, and no more than 500μA in AC and no more than 50μA in DC under a single fault.

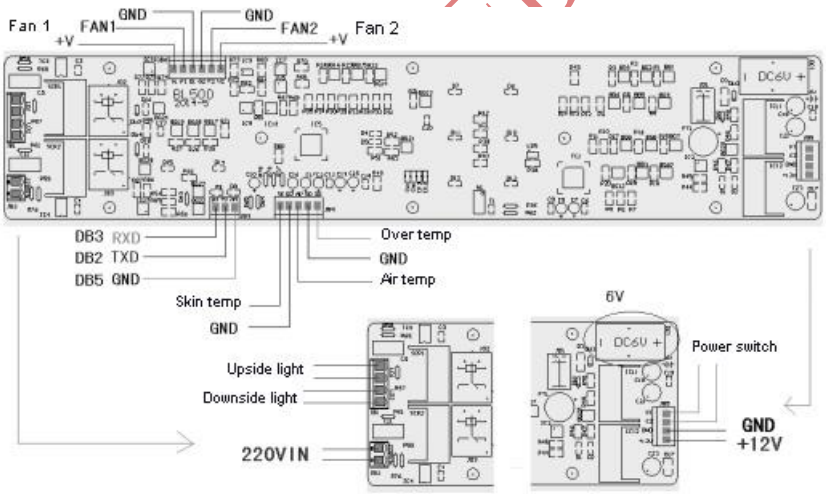
√ The parameter index in the parameter table listed in other manuals.

10 General troubleshooting

Failure phenomenon	Cause Analysis	Approach
Power failure alarm	1. Poor contact with the power socket 2. The power fuse is blown 3. Poor contact of the wiring in the control box	1. Repair or replace the power socket 2. Replace the fuse tube 3. Ask a professional to repair
Over temperature alarm	Temperature sensor is damaged	Replace temperature sensor
No display at boot	1. Forget to insert the skin temperature sensor 2. Poor contact between the skin temperature sensor and the host 3. Damaged skin temperature sensor 4. The host is malfunctioning.	1. Plug in the sensor and reboot 2. Reinsert the sensor and reboot 3. Restart after changing the sensor

Sensor alarm	1. The air temperature sensor plug falls off or has poor contact 2. The sensor is disconnected, short-circuited or damaged	1. Plug in the air temperature sensor 2. Replace the sensor
Set key operation out of control	Bad contact or damage to the unlock key	Check the unlock key for corresponding processing
The temperature display does not light up	The sensor is not plugged in or the sensor is open	Check the sensor and connect it

11 Schematic circuit diagram



If necessary, you can provide circuit diagrams, component lists, legends, calibration rules, or other information necessary for qualified technicians to help users repair equipment parts designated by the manufacturer as repairable.

12 Quality Commitment and Disclaimer

12.1 Quality Commitment

If the product described in this manual is defective in material and workmanship, it will be guaranteed for one year from the date of leaving the factory, except in the following cases:

1. All consumables and disposable items are only guaranteed free of charge for defects in delivery.

2. Confirm that it is normal maintenance and not included in the 1-year warranty period.

During the warranty period, in addition to those listed above, any defective parts can be replaced free of charge for the user.

12.2 Disclaimer

If the following conditions are found, the quality commitments proposed above are invalid, and the company does not assume any responsibility for the impact on the safety, reliability and performance of the equipment:

Failure or damage caused by the user's failure to maintain the product in accordance with the methods specified in this manual.

Failure or damage caused by user's wrong operation.

Failure or damage caused by not using parts designated by our company during maintenance or modification.

Failure or damage caused by purchase through unauthorized dealers or repairers.

Failure or damage caused by unauthorized repairers.

Failure or damage caused by unexpected events such as force majeure.

13 Packing list

Figure 13-1 Packing list

No.	Name	Unit	Qty.	Remarks
1	Host	Set	1	Including baby compartment, base, tray and drawer and control box
2	Skin temperature sensor	Set	1	
3	Main power cord	Set	1	
4	Fuse tube (T2.0AL 250V, Φ5×20)	Set	4	Spare
5	Certificate	Piece	1	
6	Instruction manual (including packing list)	Piece	1	Instruction manual (including packing list)

14 Electromagnetic Compatibility

BL-360 Infant Phototherapy Unit Device Electromagnetic Compatibility Guide and Statement

1.For this equipment, special precautions regarding electromagnetic compatibility (EMC) must be taken, and it must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.

Portable and mobile radio frequency communication equipment may affect this equipment.

2. The cables and accessories provided by this device must be used. The cable information is as follows:

Cable name	Length
Power cord	2m
Skin temperature sensor cable	1.5m

3. Except for cables (transducers) sold as spare parts for internal components, the use of accessories and cables (transducers) other than those specified may result in an increase in the emission of the equipment or system or a decrease in immunity.

4. The equipment or system should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed to verify that it can operate normally under the configuration used.

5. Basic performance

Name	Specific description
Infant Phototherapy unit	1. The equipment is turned on normally and does not affect normal use; 2. Under the interference state corresponding to the standard, the radiation light source does not appear to be off, flicker, etc, and will not trigger a false alarm.

In order to ensure that the BL-360 Phototherapy unit can be used normally and that its emission will not be increased and the immunity will not be reduced, please use the connecting cables and related accessories provided by our company.

The use of non-specified accessories or cables together with BL-360 Infant Phototherapy Unit Apparatus may result in an increase in the emission of the equipment or system or a decrease in immunity

Table 1 Guidance and declaration-electromagnetic emissions

Guidance and declaration-electromagnetic emissions
The BL-360 infant phototherapy unit is tended for use in the electromagnetic environment specified below. The customer or the user of the infant phototherapy should assure that is used in such an environment.

Emission test	Compliance level	Electromagnetic environment-guidance
RF emission CISPR 11	Group1	This equipment used RF energy only for its internal function. Therefore, its RF emission are very low and aren't likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	This equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and declaration-electromagnetic emissions

Guidance and declaration-electromagnetic emissions			
The BL-360 Phototherapy unit is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge（ESD） GB/T 17626.2	±6kVContact discharge ±8kVAir discharge	±6kVContact discharge ±8kVAir discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity

			should be at least 30%.
Electrical fast transient burst GB/T 17626.4	±2kV to power cord ±1kV pair input/output line	±2kV to power cord not applicable	The network power supply should be of the quality used in a typical commercial or hospital environment.
Surge GB/T 17626.5	±1kV line to line ±2kV line to ground	±1kV line to line ±2kV line to ground	The network power supply should be of the quality used in a typical commercial or hospital environment.
Voltage sag, short-term interruption and voltage change on the power input line GB/T 17626.11	<5%UT, lasting 0.5 cycle (On UT, >95% dip) 40% UT for 5 cycles (at UT, 60% dip) 70% UT for 25 weeks (at UT, 30% dip) <5% UT for 5 s (at UT, >95% dip)	<5% UT to 0.5 week (at UT, >95% dip) 40% UT vs. 5 weeks (at UT, 60% dip) 70% UT vs. 25 weeks (at UT, 30% dip) <5%UT to 5 s (at UT, >95% dip)00000	The network power supply should have the quality used in a typical commercial or hospital environment.

Power frequency magnetic field （50Hz） GB/T17626.8	3A/m	3A/m	The power frequency magnetic field should have the level characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment
Note: UT refers to the AC network voltage before the test voltage is applied.			

Table 3 Guidelines and manufacturer's declaration-electromagnetic immunity

Guidelines and manufacturer's declaration-electromagnetic immunity			
The BL-360 phototherapy unit device is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment.			
Immunity test	IEC 60601 Test level	Coincidence level	Electromagnetic environment-guide

Table 4 Recommended isolation distance between portable and mobile radio frequency communication equipment and BL-360 phototherapy device

Recommended isolation distance between portable and mobile radio frequency communication equipment and BL-360 infant phototherapy device	
The BL-360 phototherapy device is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile radio frequency communication device (transmitter) and the BL-360 phototherapy device.	
Rated maximum	Separation distance according to frequency of transmitter (m)

output power of transmitter W	150kHz-80MHz $d=1.2\sqrt{P}$	80MHz-800MHz $d=1.2\sqrt{P}$	800MHz～2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the frequency column of the corresponding transmitter, where P is the emission provided by the transmitter manufacturer The maximum rated output power of the machine, in watts (W).

Note 1: At 80MHz and 800MHz frequency points, the higher frequency band formula should be used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and humans.

INFANT PHOTOTHERAPY UNIT
BL-360

MANUAL BOOK

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